VII. 510(k) Summary of Safety and Effectiveness

1. Manufacturer and Contact Information:

Manufacturer:	Best Medical International, Inc. 7643 Fullerton Road Springfield, VA 22153
Contact Information:	Sankara Ramaswamy Director, Regulatory Affairs Best Medical International, Inc. (703) 451-2378, Ext. 107

2. Device Classification Name:

Pursuant to 21 CFR 892.5730, both the Best Radiopaque Strand and the Best Radiopaque Marker are class II devices.

Proprietary Name:	Best Radiopaque Strand Best Radiopaque Marker
Common/Usual Name:	Best Marker Strand Best Marker
ClassificationName:	Best Implantable Marker Strand Best Implantable Strand

3. Intended Use:

Please see Appendix 2 below titled, "Indications for Use Form".

4. Device Description and Characteristics:

The Best Radiopaque Strand (marker strand) is composed of two radiopaque markers, separated by absorbable spacers, and enclosed in an absorbable strand. It is supplied sterile.

The Best Radiopaque Marker (marker) is composed of a radiopaque non-radioactive seed (gold, platinum, stainless steel, titanium, or tungsten) which is supplied non-sterile.

The placement of the markers and marker strand in soft tissue, prior to therapeutic procedures, allows better dosimety coverage of the targeted site due to clearer identification of the anatomic regions.

5. Summary of Safety and Effectiveness:

   This 510(k) Summary of Safety and Effectiveness is in accordance with the requirements of the Safe Medical Devices Act (SMDA) 1990, and is provided in Appendix 1 below.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 9 2004

Dr. Joseph C. Whang
Official Correspondent
Best Medical International, Inc.
7643 Fullerton Road
SPRINGFIELD VA 22153

Re: K043117
Trade/Device Name: Best Radiopaque Strand
Regulation Number: 21 CFR 892.5730
Regulation Name: Radionuclide brachytherapy source
Regulatory Class: II
Product Code: 90 KXK
Dated: November 11, 2004
Received: November 10, 2004

Dear Dr. Whang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

BEST MEDICAL INTERNATIONAL, INC.

Proprietary

Appendix 2

Indications for Use Form K043117

510 (k) Number: Reference xxx

(1) Device Name: Best Radiopaque Strand

Indications For Use:

The Best Radiopaque Strand (Marker Strand) is made of radiopaque xxx[a] markers (i.e, seeds) and absorbable spacers, inside an absorbable strand, is indicated for use in brachytherapy, soft tissues, or organ tissue, but should not be used during cardiovascular or neurological procedures.

(2) Devise Name: Best Radiopaque Marker

Indications For Use;

The Best Radiopaque Marker (Marker) is made of a radiopaque xxx[a] solid seed, is indicated for use in brachytherapy, soft tissues, or organ tissue, but should not be used during cardiovascular or neurological procedures.

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a gold, platinum, stainless steel, titanium, or tungsten

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use / (Per 21 CFR 801.109) OR Over-The-Counter Use

David A. Lagomarsino

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K043117